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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,333	10/22/2001	Lisa P. Weinberg	A01P1078	9773

36802 7590 10/04/2004
PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

GETZOW, SCOTT M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/04/2004

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,333

Applicant(s)

WEINBERG ET AL.

Examiner

Scott M. Getzow

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-15 is/are allowed.
- 6) ☒ Claim(s) 16-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 16, 17, 19, 22, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al (6006134).

Figures 16-19 show a transvenous lead that has an insulating sheath, and at least one conductor connected to a proximal connector. Column 2, lines 60-67 teach that the transvenous leads are meant to be located in a vein adjacent nerve fibers to be stimulated, and that the invention can be part of an implantable stimulator device. Column 8, line 21 teaches that the catheter can be used in the azygos vein, and lines 6+ teach that stimulating the right vagal nerve to reduce heart rate is known in the art. Column 7, lines 22+ teach that the catheter can be used in the SVC. Column 9, line 24 teaches that a preformed bend can be made in the lead to properly position the lead for vagal stimulation. Thus, the Hill device teaches all of the structure of the above claims. For the lead to make contact with tissue proximate to the cardiac branch of the right vagus nerve is considered to be implicitly accomplished, or capable of being accomplished, by the lead of Hill. Further, the placement is considered to be intended use that relates to the method of using the lead.

Claim Rejections - 35 USC § 103

3. Claims 20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al in view of Dahl et al (6697677).

To use an expandable basket type electrode array, as shown by Dahl (see figures 11,12), would have been obvious since such is known in the art to provide secure contact with the walls of the vascular system of a patient.

4. Claims 18,24-28,31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al in view of Warman et al (6201994).

Warman teaches a single pass lead with electrodes in the SVC, coronary sinus, atrium, and ventricle. It would have been obvious to use to use a single lead, as shown by Warman, since such would reduce the complexity of the device, as well as cost. As mentioned above, Hill teaches an implantable device that contains a vagal module used for vagal stimulation. Hill also teaches the use of atrial and ventricular electrodes, see figure 16. Hill also teaches that an electrode can be used in the SVC. The structure of the above combination could deliver stimulation pulses to the atrium, if so desired, and thus encompasses the functional language of the claim 27. Regarding claim 18, Warman shows arms 272 in figure 9. The ordinarily skilled artisan would realize that such arms could be used to be inserted in a nearby vessel.

Art Unit: 3762

5. Claims 29,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al and Warman et al and further in view of Dahl.

It would have been obvious to use the expandable electrode of Dahl for reasons mentioned supra.

Since new rejections have been made, this action is not made final.

Allowable Subject Matter

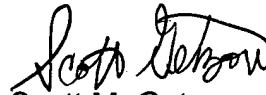
6. Claims 1-15 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (703) 308-2997. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Scott M. Getzow
Primary Examiner
Art Unit 3762

Smg